IV. SMDA INFORMATION

A. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:	BD Ophthalmic Systems
• Address:	411 Waverly Oaks Road BLG 2, Suite 229 Waltham, MA 02452-8405
• Registration Number:	1226073
• Contact Person:	Eileen T. Schweighardt Regulatory Affairs Manager Tel No. 201-847-4570 Fax No. 201-847-4881
• Date of Summary:	August 5, 2002
Device	
• Trade Name:	BD K-3000™ Microkeratome System
• Classification Name:	Keratome and Accessories
• Classification:	Class I (reserved)
• Performance Standards:	None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

• Device Description

The BD K-3000™ Microkeratome System is a battery operated, fully automated Keratome intended device to produce a corneal resection prior to laser ablation for refractive surgical laser applications and procedures such as, in Laser In-situ Keratomileusus (LASIK) surgery. The Microkeratome is a precise cutting device uniquely designed for added comfort, speed and accuracy. The BD K-3000™ Microkeratome System enables surgeons to cut precision flaps quickly and easily. The Microkeratome's unique shape is designed to offer more comfort and efficiency while delivering precision and accuracy. The Microkeratome system features:

- One-piece fully assembled handpiece allows complete assembly prior to positioning on the eye
- The handpiece is ergonomically designed and of titanium construction to increase surgeon comfort
- All components are fully interchangeable for flexibility
- The keratome system consistently produces a corneal resection of a predetermined diameter, thickness and uniform surface quality.
- The keratome head assures depth consistency. The head houses a precision blade and delivers constant drive alignment through a double dovetail suction ring.
- The keratome handpiece contains dual motors. One controls oscillation of the blade and a second translates the head across the eye.
- The keratome handpiece automatically returns to home position without oscillating.

• Intended Use

• The BD K-3000™ Microkeratome System is a battery powered device intended to produce a corneal resection for refractive laser applications and procedures in Ophthalmic surgery, such as in Laser In-situ Keratomileuses (LASIK) surgery. The corneal resection is consistently of a predetermined diameter, thickness and uniform surface quality for precise lamellar cuts and consistent flap generation.

Summary of Performance Study Results

Keratomes have been used for lamellar (partial thickness) resections for more than 30 years. More recently, June 21, 2001 the FDA, ODE, Diagnostics and Surgical Devices Branch, Division of Ophthalmic and Ear, Nose and Throat Devices has recognized keratomes can be labeled with LASIK indications in refractive surgery.

Performance evaluation utilizing in-vitro studies on porcine eyes demonstrated:

- Flap thickness consistency, accuracy and variability
- Safety of corneal resection
- Good quality of corneal resection

Four (4) experienced surgeons rated the quality of the stromal bed after corneal resection of porcine eyes and qualitatively evaluated the Microkeratome blade sharpness and corneal resection quality.

The performance of the principle device in operation as a total system is substantially equivalent to the predicate device offering no new questions of safety or effectiveness.

III. Predicate Device Summary Table

• Substantial Equivalence

Based upon the comparison of the intended use, technology and principles of operation, design and materials, the BD K-3000™ Microkeratome system can be shown to be substantially equivalent to the commercially available predicate devices indicated in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Insight Technologies Inc. Technology rights acquired by BD Ophthalmic Systems	BD K-3000™ Microkeratome System (formerly ITI Keratome Model K-3000)	K 984537	May 14,1999
Microspecialties Inc.	Microkeratome Blade with Holder For ITI Keratome System	K-980510	May 1, 1998

Eileen Schweighardt 8-5-02

Eileen T. Schweighardt
Regulatory Affairs Manager
Becton Dickinson Ophthalmic Systems
Becton Dickinson and Company

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2002

Becton Dickinson & CO.
c/o Ms. Eileen Schweighardt
Manager of Regulatory Affairs
1 Becton Drive
Franklin Lakes, NJ 07417

Re: K022637
Trade Name: BD K-3000™ Microkeratome System
Classification Regulation Number: 886.4370
Regulation Name: Keratome
Regulatory Class: I
Product Code: HMY
Dated: August 7, 2002
Received: August 8, 2002

Dear Ms. Schweighardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. STATEMENT OF INTENDED USE

510(k) Number (if known): K022637

Device Name: BD K-3000™ Microkeratome System

Indications for Use:

The BD K-3000™ Microkeratome System is a battery powered device intended to produce a corneal resection for refractive laser applications and procedures in Ophthalmic surgery, such as in Laser In-situ Keratomileuses (LASIK) surgery. The corneal resection is consistently of a predetermined diameter, thickness and uniform surface quality for precise lamellar cuts and consistent flap generation.

(Please do not Write below this line-continue on another page if needed)

(Division Sign-Off) Jean I Kaufman
Division of Ophthalmic Ear,
Nose and Throat Devises

K022637

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use_____

(Per 21 CFR § 801.109)

(Optional format 1-2-96)

000021